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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/692,314	08/05/1996	ROBERT N. HAMLIN	910458.CDA	3428

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07/01/2002

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EXAMINER

DYE, RENA

ART UNIT

PAPER NUMBER

3627

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/692,314

Applicant(s)

HAMLIN, ROBERT N.

Examiner

Rena L. Dye

Art Unit

3627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 206-218 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 206-214 and 216-218 is/are rejected.
- 7) ☒ Claim(s) 215 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2002 has been entered.

Status of the Claims

2. Claims 206-218 are currently pending in this application.

Claim Rejections - 35 USC § 112

3. Claims 206-214 and 216-218 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the "Summary of the Invention" in the present specification, Applicant discloses that a tensile layer is combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer (page 2, last paragraph). Therefore, Applicant's specification does not clearly support a layer of PEEK or PEK located as an *inner tensile* layer, or a different polymeric layer as the outer layer. The PEEK or PEK layer should be claimed as the outer layer, or

Art Unit: 3627

external to the inner layer, and the second layer recited as the inner layer, as supported by the present specification.

With respect to the recited, “a second extruded layer comprising a second polymer material different from the first polymeric material” recites limitations broader than the disclosed invention will support. Applicant’s specification specifically discloses that the inner layer is a physically compatible adhesion or bonding layer. Therefore, providing a polymeric material layer different than the first polymeric material layer may not provide the function of an adhesion or bonding layer as is supported by the present disclosure. Applicant’s claims are recited more broadly than the present specification will support.

Allowable Subject Matter

4. Claim 215 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to teach or suggest a medical balloon catheter comprising a multilayer balloon having an extruded tensile layer comprising a first polymeric material selected from a group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and a second extruded layer comprising a second polymeric material different from the first polymeric material;

wherein the second layer is an adhesion layer; and the adhesion layer is disposed toward the interior of the balloon relative to the tensile layer, which is disposed toward the exterior.

Response to Arguments

5. Applicant's arguments filed on May 14, 2002 have been fully considered but they are not persuasive.

The Examiner has carefully considered Applicant's arguments filed with the response. Applicant's argument that the Examiner's reasoning is inconsistent with Applicant's disclosure, which explicitly discloses that a material can be used both in the tensile layer and in the inner layer is not well understood and requires further clarification. Applicant specifically discloses that PEEK and PEK are listed as examples of materials exhibiting the required high tensile (page 3, lines 14-28), in which the tensile layer is to be used as the outer layer (page 2, lines 32-34). Nowhere in the paragraph found on page 3, lines 1-13 does Applicant mention that PEEK or PEK can be used as a suitable adhesion material or inner layer. The Examiner acknowledges that the present specification at pages 3-4 discloses that PVC can be used as a tensile layer as well as an adhesion layer, however, the Examiner would like to note that the tensile PVC is listed as ABS/PVC which is understood by the Examiner to have the meaning of a blend of ABS and PVC or a copolymer thereof. Furthermore, Applicant's argument regarding the use of PVC as an inner or an outer layer is not relevant to the teaching of PEEK or PEK as an inner or outer layer, because PEEK and PEK are not specifically disclosed for use in both layers.

The present specification specifically discloses at page 2, line 20 through page 3, line 28 under the heading of "Summary of the Invention" that:

It has been found that a layer of medium or relatively high melt temperature material which also exhibits high tensile strength with relatively low distensibility be used to provide the

Art Unit: 3627

required high burst or tensile strength and low radial expansion at high pressures required by the expander member in a composite structure... ..In the composite structure, the tensile layer is combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer which is fabricated from materials having superior glue bonding or melt bonding characteristics.....The bonding layer imparts the necessary adhesion properties to properly bond the expander member to the distal end portion of the catheter body (emphasis added). Examples of material exhibiting the required high tensile, low distensibility and having medium melt temperatures include ... polyetheretherketone (PEEK) and polyetherketone (PEK).

Therefore, it appears from Applicant's disclosure that a claim reciting an outer layer of PEEK or PEK layer (tensile layer) and a second inner layer (bonding layer) would be supported by Applicant's specification. The present specification would also support a PEEK or PEK layer which is external to the *bonding* layer. The specification, however, does not clearly support providing a PEEK or PEK layer as the inner layer, or a layer inside of the second layer or bonding layer, which would be included or encompassed by the undue breadth of the present claims. The specification specifically names PEEK and PEK as materials that exhibit the required high tensile strength and have medium melt temperatures. From this disclosure the PEEK or PEK layers would not provide the necessary bonding properties, *i.e.* lower melting point than the tensile layer (page 3, lines 4-6 of the spec.), to bond the expander member to the distal end of a catheter body.

The Examiner is not attempting to unduly limit Applicant's claimed invention to that which is a preferred embodiment. The Examiner is, however, attempting to limit Applicant's claimed invention to that which is clearly set forth as his invention at the time of filing, *i.e.* that

Art Unit: 3627

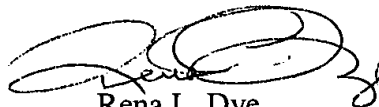
which is broadly set forth at page 2, line 20 through page 3, line 28 as the present specification.

The present disclosure does not clearly support the use of PEEK or PEK used in various layers with respect to the location of an inner or outer layer of the balloon catheter, or in any combination with respect to the second layer. It is the Examiner's position that one having ordinary skill in the art at the time of Applicant's invention would not have derived the claimed invention from the present disclosure. Accordingly, the rejection under 35 USC § 112, first paragraph, has been maintained as set forth above.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday -Thursday 8:30 AM - 7:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703-308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9326 for regular communications and 703-872-9327 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.



Rena L. Dye
Primary Examiner
Art Unit 3627

R. Dye
June 29, 2002